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Differences between Serious and Non-Serious Patient Safety Incidents in the Largest Hospital District in Finland

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Abstract

Objectives: To determine if and in what ways serious patient safety incidents differ from non-serious patient safety incidents.

Methods: Statistical analysis was performed on patient safety incident reports that were reported in 2015 in Finland's largest hospital district (Helsinki and Uusimaa, HUS). Reports were divided into two groups: non-serious incidents and serious incidents. Differences between groups were studied from several types of categorically divided information.

Results: Of the total amount of reports (15 863) 1 % were serious incidents (175). Serious and non-serious incidents differed significantly from each other. Serious incidents concerning laboratory, imaging or medical equipment were more common. On the other hand incidents concerning medication, infusion, blood transfusion, were less frequent. In serious incidents the proportion of doctors reporting was greater and contributing factors were better recognized, the most common of them being working of procedures.

Conclusions: In the future, special attention should be given to the particular aspects of serious patient safety incidents, such as safe use of medical equipment, training and handling of procedures. Root cause analysis is an effective way to handle serious incidents and enables the prevention of their reoccurrence. However, a systematic follow of the root cause analysis should be developed.

MeSH keywords: patient safety, patient harm, medical errors, risk management

1 Introduction

Scientific research on patient safety began in the 1980s, especially in the United States (1). In Finland, research on this subject began vigorously only in the early 2000s. In 2009, the Ministry of Social Affairs and Health in Finland announced for the first time a national patient safety strategy and in 2011 a plan for quality management and for ensuring patient safety was published and implemented in Finnish legislation (2, 3). Also currently training programs for health care professionals on patient safety (4) and a nationwide reporting system for incidents and near miss events have been implemented in the health care system.

A patient safety incident (safety incident) is an adverse event compromising patient safety that could have or did lead to patient harm. Most of these are non-serious patient safety incidents (non-serious incident). However, serious patient safety incidents (serious incident) are also reported. A serious incident is an event that leads to substantial, serious or permanent harm to patient, causes serious danger to the life or safety of the patient, or is a patient safety incident concerning a large group of patients. Serious harm is a consequence from an event that leads to a patient's death, commencement or continuation of hospitalization, serious impairment, disability or an event that is life-threatening (5, 6). Serious incidents form a small but significant fraction of safety incidents and it is important to study their nature and prevalence.

The aspects of human error, especially from the view of human factors, are widely covered by Reason (7). He divides human action into routine processes, more unfamiliar situations and novel situations. In each situation certain type of errors are expected: slips and lapses; rule-based mistakes; and knowledge based mistakes respectively.

The current scientific view on human error emphasizes the system approach, according to which working environments and organizational processes are such that errors are expected (8, 9, 10). In addition, working procedures at all levels of the organization drift towards procedures that are more likely to cause errors (9, 10). Therefore, organizations must have processes through which procedures are monitored, incidents are reacted to and lessons are learned from them and finally, future events are anticipated (9).

Improving patient safety is essential from both humane and economical perspectives. In Finland, the Finnish Patient Insurance Centre handles all personal injuries that occur in connection with healthcare activities. It compensates annually about 2200 patient injuries and their costs are about 41 million euros (11). Much of the costs of medical errors are, however, covered either by health care units in their extra costs or by patients themselves due to prolonged disabilities and suffering.

2 Methods

The purpose of this study was to determine if and in what ways serious incidents differ from non-serious incidents. An additional objective was to identify the nature and number of both types of incidents.

All Finnish hospital districts, together more than 144 000 health care professionals, use a common system for reporting patient safety incidents (HaiPro). HaiPro reporting program has been developed by Awanic® and has been used since 2009. Finland is divided into 19 hospital districts. Helsinki and Uusimaa District (HUS) is the largest hospital district in Finland and is further divided into five regionally determined hospital areas. HUS also runs the largest academic teaching hospital in Finland (Helsinki University Hospital), which covers all medical specialties in tertiary care and emergency services within the district. The

number of patient safety reports continues to rise annually. Data consisted of HaiPro reports generated in the HUS district in 2015. (4)

Patient safety at HUS is promoted through the principles of risk assessment. Risk assessment is the process through which organizations develop an understanding of the risks they face (12). The Patient Safety Development Program at HUS is coordinated by the Chief of Patient Safety and e.g., the patient safety surveillance is guided by the steering committee which monitors patient safety data on a regular basis.

2.1 HaiPro reporting system

The HaiPro reporting form is an easy-to-fill, e-form and can be accessed from the HUS intranet homepage by anyone who works for HUS. It can be done anonymously and employees are strongly encouraged to report incidents. The HaiPro system is not yet available for patients (4). A separate procedure for reporting and analyzing severe patient safety incidents has been in use since 2013. In the electronic HaiPro form, several types of categorically divided information are selectable from dropdown menus. In this study, the HaiPro categories are *italicized*. The administrative unit of the incident and of the employee, occupation, time of incident, place of incident, nature of incident *(actual* or *near miss*) and finally type of incident are selected. In addition, what happened, the consequences of the incident, contributing factors and what could be done to avoid similar incidents in the future are recorded. After submission, the report is automatically forwarded for analysis by a doctor-nurse pair that is responsible for patient safety in the given unit.

Analysis begins by specifying and by changing the type of incident, which can be specified from fifteen categories and several subcategories. Additional information can be requested from the person who filed the report. The degree of harm is specified and the consequences

for the unit are selected. Next, the level of risk is determined by assessing the likelihood of reoccurrence and the severity of the consequences using the HaiPro risk matrix (Figure 1). Control of the situation and immediate actions are also specified. The possible contributing factors are specified (ten categories, several subcategories). Finally, the preventive action is specified (four categories, several subcategories). The handling of a safety incident report is illustrated in Figure 2.

The analysis of serious incidents differs from the procedure depicted earlier. A separate root cause analysis (RCA) is coordinated by a serious incident analyst. If the degree of harm is specified as *serious* or the incident has a risk level of IV or V, the report is automatically directed to the serious incident analyst who then confirms the serious incident procedure or returns the report to the regular safety incident analysis with explanation for the return. If needed and if contact information is available, the serious incident analyst can request for additional information from the person who filed the report. All serious incidents are transferred to a higher level of organization and discussed in a multi-professional group led by the serious incident coordinator. The chain of events is analyzed using the Ishikawa procedure (13). With this method, particular causes that lead to the effect are identified. For each effect, the actions promoting patient safety and the persons responsible for the actions are defined and a deadline is given. After the RCA, the person marked as responsible for the actions required receives an email about the task. The serious incident report is marked as completed after all the necessary actions are performed.

2.2 Data and Statistical Methods

HaiPro reports were divided into two groups: non-serious incidents and serious incidents. Groups were created 2016/3/3. To determine how non-serious incidents and serious incidents differed in their nature, the number of reports in each category (e.g. type of

incident: *medical equipment or its operation*) was compared between the groups using a Chi-squared test. The results from the main categories are the focus of this study. A cut-off p value of 0.05 was used to evaluate statistical significance. If the number of reports was too small to perform the test reliably, they were excluded (N/A, not available)

3 Results

3.1 HaiPro reports in HUS district

In the year 2015 there were in total 15 863 HaiPro reports made in the HUS district. Of these, 15 688 were non-serious incidents and 175 (1 %) were serious incidents.

In Hospital area 1 (including university hospital), the number of non-serious incidents was 10 406 and serious incidents 100. The range of serious incident percentages between Hospital area 1 units was 0.2 % to 3.8 %. The range of percentages between Hospital areas was 0.7 % to 2.4 %. The greatest percentage of serious incidents in Hospital area 1 (n = 38, 3.8 %) was reported in the unit including *operating rooms, intensive care and pain management*. (Table 1.)

3.2 Non-serious incidents, serious incidents and their differences

According to this study, there are statistically significant differences in the nature between serious and non-serious incidents. It is noteworthy, that serious incidents were more commonly concerned with laboratory tests and medical equipment and that the most common contributing factor was handling of procedures.

The greatest proportion of the serious incidents happened in *patient rooms* (non-serious 4284 [27 %], serious 60 [34 %], $p < 0.05$) and *operating rooms* (non-serious 801 [5 %], serious

26 [15 %], $p < 0.05$). In *laboratory* the proportion of incidents between groups was equal (non-serious 1638 [10 %], serious 16 [9 %], $p > 0.05$). Regarding weekdays, there were no differences between groups. In both groups, errors in working days were more common than in Saturdays and Sundays. (data not shown)

Doctors filed a greater proportion of serious incidents (non-serious 763 [5 %], serious 28 [16 %], $p < 0.05$). However, in both groups *nurses* filed the reports most often (non-serious 11 388 [73 %], serious 107 [61 %], $p < 0.05$). Incidents that actually happened were reported more often in serious incidents (non-serious 9037 [58 %], serious 139 [79 %], $p < 0.05$). Near miss reporting was more common among nurses and other personnel. In serious incidents the degree of harm was most commonly *serious* (33 %) (data not shown).

The summary of incident types is shown in Table 2. The most common serious incidents were *Laboratory, imaging or other tests* (non-serious 2754 [18 %], serious 41 [23 %], $p < 0.05$) followed by *other treatment or monitoring* (non-serious 1282 [8 %], serious 26 [15 %], $p < 0.05$) and *medical equipment or its operation* (non-serious 880 [6 %], serious 23 [13 %], $p < 0.05$). The most common non-serious incident was *Medication, infusion, blood transfusion, contrast medium* (non-serious 5900 [38 %], serious 25 [14 %], $p < 0.05$). It was the fourth most common among serious incidents.

As for the specific type of incident within serious incidents the most important were: sample taken from the wrong patient (*Laboratory, imaging or other tests*), monitoring neglected or the need for it not recognized (*other treatment or monitoring*) and equipment malfunction (*medical equipment or its operation*) (data not shown).

A greater proportion of the consequences for the unit in serious incidents were *extra work, minor extra treatment* (non-serious 8084 [52 %], serious 118 [67 %], $p < 0.05$) and *harm to*

unit image (non-serious 4339 [28 %], serious 73 [42 %], $p < 0.05$). In addition, in serious incidents, a clear difference was seen in *longer stay of care* (non-serious 609 [4 %], serious 49 [28 %], $p < 0.05$) and *extra costs* (non-serious 684 [4 %], serious 32 [18 %], $p < 0.05$).

A summary for contributing factors is shown in Table 3. In serious incidents, *not known* presented a smaller proportion (non-serious 4001 [26 %], serious 15 [9 %], $p < 0.05$). On the other hand, the most common contributing factor in serious incidents was *handling of procedures* (non-serious 2985 [19 %], serious 62 [35 %], $p < 0.05$). Also more common in serious incidents were *training, orientation and skills* (non-serious 1212 [8 %], serious 27 [15 %], $p < 0.05$) followed by *medical device and equipment* (non-serious 601 [4 %], serious 23 [13 %], $p < 0.05$).

Proposals for preventive actions differed in each category between groups. Common serious incidents included *decision to a higher organizational level* (non-serious 380 [2 %], serious 42 [24 %], $p < 0.05$), *no actions needed* (non-serious 1938 [12 %], serious 38 [22 %], $p < 0.05$) and *plan a procedure to prevent future incidents* (non-serious 640 [4 %], serious 30 [17 %], $p < 0.05$). The proportion of *inform/discuss about the incident* (non-serious 12 298 [78 %], serious 72 [41 %], $p < 0.05$) was significantly smaller in serious incidents but was the greatest category in both groups.

4 Discussion

To our knowledge, there are no previous studies in the English literature that focus on the differences between non-serious and serious incidents. Thus, this study brings new and more specific scientific evidence on the nature of patient safety incidents.

Ruuhilehto et.al. analyzed all safety incidents made with the HaiPro system in Finland from 2007-2009 (14). Regarding non-serious incidents, findings are consistent with our study. However at that time separate RCA for serious incidents was not in use.

The National Health Service England (NHS) publishes quarterly reports from the National Reporting and Learning System (NRLS). Data is available from all safety incidents. Serious incidents are directed to a separate serious incident management process and public data containing only serious incidents is not available. In 2014, the most common type of incident in the NRLS data was *patient accident* (19 %). When analyzing the combined number of incidents with degree of harm *serious harm* and *death*, the most common type of incident was *implementation of care and ongoing monitoring / review* (19 %) (15). This is in accordance with our study where *other treatment or monitoring* was more common in serious incidents.

In Finland, health care professionals receive training for the use of HaiPro. Use of incident reporting systems as such improves patient safety. Furthermore, the training received by health care professionals increases their knowledge about safety culture, which in turn also improves patient safety (16, 17, 18). Especially with regards to this study, the level of organizational safety culture may also impact the degree of safety incident seriousness (19). In general, health care organizations should specifically work to create a nonpunitive safety culture in order to improve patient safety (20). The number of incident reports in Finland has risen annually, which is indicative of improving patient safety culture and increasing patient safety in general.

According to our study, about 1 % of all safety incidents in HUS are serious, which is in accordance with other studies (14, 15, 16). However, only about 2 % of patients are involved in a safety incident, when compared to the total number of treated different patients. This

finding does not correspond to other studies, according to which approximately 10 % of patients are involved in a safety incident (21). This discrepancy may be a sign of underreporting. There are no previous studies in Finland that consider how many of the incidents actually get reported. According to some studies, approximately 20 % of the employees admit omitting a non-serious incident report and about 4 % admit that they have not filed a report after a serious incident (22, 23). Incident reporting willingness in Finland should be further studied.

In both groups, nurses had submitted the majority of reports, which is consistent with previous studies (22, 24, 25). However, the portion of reports submitted by doctors was three times higher in serious incidents. It seems that the employees' willingness to report incidents increases with severity of incidents (22), but to our knowledge there are no studies that try to resolve the differences regarding doctors' willingness to report serious versus non-serious incidents. According to other studies, doctors' willingness to report safety incidents in general is reduced, for example, by insufficient training on patient safety, fear of blame, embarrassment, fear of consequences for their future career or the belief that it is not their responsibility to report others' mistakes (22, 24, 25). On the contrary, willingness to report increases if the reporting provides a possibility to learn from mistakes (26), feedback is given and reports are kept confidential (27). The increased amount of serious incident reports by doctors may in part arise from the fact that doctors perform more risky procedures and that doctors are legally responsible for patient care (3). In conclusion, it seems that doctors´ activity increases when incidents are serious. The RCA Tool developed by the hospital district facilitates a structured process for an analysis of serious cases. This further promotes willingness to report serious incidents, especially when they are handled nonpunitively. This phenomenon is suggested for future research.

The number of reports in both groups was twice as large on working days compared to reporting on weekends. This is explained at least in part with the corresponding allocation of elective operations on weekdays. In addition, weekday was the only type of data where there were no statistically significant differences between groups.

Harm to unit image was almost twice as common of a consequence for the unit in serious incidents compared to non-serious incidents. This finding may in part reflect undeveloped patient safety culture and employees' beliefs that a serious incident is shameful. If this is the case, employees in a way have not accepted the fact that mistakes can happen anytime and to anyone (7, 8, 9 and 10). Additionally, *longer stay of care* and *extra costs* were more common consequences for the unit in serious incidents. According to this study, serious incidents are critical for the institution from the economical perspective. Further, in serious incidents the degree of harm was usually *serious*. Therefore serious incidents are critical also for the patient from humane perspective. Targeted patient safety training directed decreasing the serious incidents can not only reduce human suffering but also reduce total costs (16, 17, 18).

Other studies, as well as ours, have found medication-related incidents to be most common (15, 28). However, in our study among serious incidents medication-related incidents were only the fourth most common type, while *laboratory, imaging or other tests* was the most common type of incident. In the NRLS data, "degree of harm by type" categories of *severe* and *death* can be combined as one category and then be compared with serious incidents in our study (15). In that case the proportion of *medication* in the NRLS data also decreased, which is in accordance with our study. In the NRLS data, *medical device / equipment* is a fairly rare category in general. This is inconsistent with our study, where *medical equipment or its operation*-related incidents were common (5,6 % of non-serious), especially in the serious incidents (13,1 %). Further studies are necessary to determine the effectiveness of

training, safe use of medical equipment and their maintenance since in this study contributing factors such as *handling of procedures* and *training, orientation and skills* and *medical device and equipment* were also more common in the serious incidents.

In the non-serious incidents, contributing factors were not known in one-fourth of the incidents, three times more than in serious incidents. It seems that in serious incidents contributing factors are recognized more effectively. Preventive actions were also more commonly reported. *Plan a procedure to prevent future incidents* or *decision to a higher organizational level* were more common in serious incidents. Therefore, the RCA where effects are identified and the actions for promoting patient safety are specified seems to be an appropriate way to handle serious patient safety incidents.

In order to achieve effective and sustainable solutions following a RCA health care organizations should consider for example institutional changes and updates in IT structures. However many smaller solutions together, such as training and counselling can also have an effective and sustainable impact on patient safety. (29)

In our study actions to be done usually included discussions with the persons involved, reminders to the personnel about applicable guidelines or processing the cases in unit meetings. Procedures were also updated and new guidelines created. Additionally, extra training was provided for the personnel or new equipment were purchased. Further studies are necessary to determine if the performed actions have an impact on patient safety. It is noteworthy, that in the HaiPro system the completion of the actions promoting patient safety are not automatically monitored. A system that follows the progression of actions promoting patient safety is required.

To summarize the findings regarding RCA, our study seems to be in accordance with the current scientific view on the matter; the method is promising but is rarely used to its full potential. In our study the most notable weakness of RCA was the lack of measuring of outcomes. There are also other widely recognized problems with RCA. For example analysis often results in a linear chain of events (who, what) rather than a more realistic systemic view (how) and the causes are expressed too vaguely. Secondly, the group performing RCA is usually a local team rather than a diverse group of expert accident investigators with a range of knowledge from subject matter to human factors and interview techniques. The results of the analysis are also rarely shared with the persons involved, persons that might come across with a similar situation, or with other units and organizations. The purpose of sharing the results, in fact the purpose of the whole RCA method, is to learn from the events and to prevent them from happening again. (30, 31, 32)

One possible solution for the shortcomings of RCA could be the use of the Human Factors Analysis Classification System specifically tailored to the health care industry (32). This method would allow for a standardized approach to identify “why” instead of “who and what”. Human and environmental factors would be more thoroughly investigated and a standardized nomenclature would provide the basis for sharing information across organizations.

There are some limitations in this study which are suggested to be taken into consideration. The main limitation is the type of HaiPro data which doesn´t represent the actual rate of incidents. However, this study does not seek to describe an incident rate but rather a descriptive analysis of the phenomenon which has seldomly been studied.

5 Conclusion

In conclusion, the HaiPro reporting system is increasingly adopted in the Finnish health care system. The systematic incident reporting procedure has been in use for a fairly short time in Finland and the number of reports continues to rise annually. The increasing number of patient safety reports is a sign of improved patient safety culture, which in turn is critical for further improving patient safety. It is likely that not all incidents are reported, so additional effort is necessary to further raise reporting willingness. Doctors' increased activity to report serious incidents should be further studied. In the future, special attention should be given to the particular aspects of serious patient safety incidents, such as safe use of equipment, training and procedures. A system that follows the progression of the actions for promoting patient safety should be developed.

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Table 1. HaiPro reports in HUS Hospital areas (including Hospital area 1 units separately). Table presents the numbers of safety incidents, non-serious incidents, serious incidents and the percentage of serious incidents in relation to all safety incidents (%). Information is given from each Hospital area.

Hospital area 1	safety incident	non-serious	serious	%
children's and juvenile diseases	1575	1570	5	0.3 %
psychiatry	1147	1132	15	1.3 %
acute	1027	1022	5	0.5 %
head and neck	1008	1004	4	0.4 %
operating rooms, intensive care, pain management	990	952	38	3.8 %
oncology	878	876	2	0.2 %
abdominal	826	822	4	0.5 %
heart and lung	791	782	9	1.1 %
gynecology and labor	643	631	12	1.9 %
rheumatic diseases and plastic surgery	619	617	2	0.3 %
internal medicine and rehabilitation	561	558	3	0.5 %
inflammation	441	440	1	0.2 %
Hospital area 1, total	10506	10406	100	1.0 %
Hospital area 2	1158	1143	15	1.3 %
Hospital area 3	926	919	7	0.8 %
Hospital area 4	536	532	4	0.7 %
Hospital area 5	248	242	6	2.4 %
HUSLAB	2043	2000	43	2.1 %
HUS imagining	277	277	0	0.0 %
Other (e.g. administrative, catering, maintenance)	169	169	0	0.0 %
HUS, total	15 863	15 688	175	1.1 %

Table 2. Type of incident

Table presents the division of reports among type of incident for non-serious and serious incidents. To ease interpretation, bolded numbers are used for the groups where the percentage of incidents is greater and the difference is statistically significant. (n = number, % = percentage of reports compared to group total)

Type of incident	non-serious		serious		p value
	n	%	n	%	
Medication, infusion, blood transfusion, contrast medium	5900	37,6	25	14,3	< 0.001
Information transfer and handling, communication	3659	23,3	31	17,7	0.081
Laboratory, imaging or other tests	2754	17,6	41	23,4	0.043
Other treatment or monitoring	1282	8,2	26	14,9	0.001
Medical equipment or its operation	880	5,6	23	13,1	< 0.001
Accident	696	4,4	15	8,6	0.009
Other	637	4,1	12	6,9	0.063
Violence	311	2,0	11	6,3	< 0.001
Asepsis/hygiene	264	1,7	1	0,6	N/A
Physical surroundings	233	1,5	3	1,7	N/A
Invasive procedure	214	1,4	10	5,7	< 0.001
Surgical operation	174	1,1	6	3,4	N/A
Diagnosis	101	0,6	4	2,3	N/A
Radiotherapy	74	0,5	0	0,0	N/A
Not known	32	0,2	0	0,0	N/A
First aid environment	16	0,1	0	0,0	N/A

Table 3. Contributing factors

Table presents the division of reports among contributing factors for non-serious and serious incidents. To ease interpretation, bolded numbers are used for the groups where the percentage of incidents is greater and the difference is statistically significant. (n = number, % = percentage of reports compared to group total)

Contributing factors	non-serious		serious		p value
	n	%	n	%	
Not known	4001	25,5	15	8,6	< 0.001
Handling of procedures	2985	19,0	62	35,4	< 0.001
Communication and information transfer	2772	17,7	28	16,0	0.564
No contributing factors, normal situation	2181	13,9	23	13,1	0.773
Environment, facilities, resources	1777	11,3	19	10,9	0.845
Training, orientation and skills	1212	7,7	27	15,4	< 0.001
Patient and relatives	665	4,2	17	9,7	< 0.001
Medical device and equipment	601	3,8	23	13,1	< 0.001
Teamwork	489	3,1	18	10,3	< 0.001
Organization, management	121	0,8	12	6,9	< 0.001
Medication	81	0,5	3	1,7	N/A

Figure 1.

Risk Matrix Used with HaiPro Analysis

	HaiPro risk matrix [translation from Finnish by author]		
		Consequences	
Likelihood	**Minor** Discomfort, delayed or prolonged treatment without substantial health effects	**Major** Health effects requiring treatment, prolonged treatment, temporary incapacity for work	**Severe** Death, permanent or serious harm, permanent incapacity for work
Remote random event, short time exposure	I Negligible risk	II Low risk	III Moderate risk
Probable Near miss events have happened	II Low risk	III Moderate risk	IV High risk
Frequent Incidents have happened, near miss events happen frequently	III Moderate risk	IV High risk	V Serious risk

Figure 2.

Handling of a Safety Incident Report in the HaiPro System